Indiana State Department of Health

Economic Impact on Small Business Statement Pursuant to IC 4-22-2.1

LSA # 05-321
Serious Adverse Event Reporting Rule
410 IAC 15-2.4, 410 IAC 26, 410 IAC 27

March 9, 2006

Description of Rule:

The Indiana State Department of Health (ISDH) has responsibility for the licensure and regulation of ambulatory surgery centers, abortion clinics, and birthing centers pursuant to IC 16-21. In January 2005, Governor Daniels issued Executive Order 05-10 requiring the ISDH to develop and implement a medical errors reporting system (MERS). In response to the Executive Order, the ISDH Hospital Council recommended and the ISDH Executive Board preliminarily adopted rules requiring the reporting of medical errors.

The proposed rule is based on the National Quality Forum's twenty-seven (27) serious reportable events or 'never' events as they are frequently called. The proposed rule requires ambulatory surgery centers, abortion clinics, and birthing centers to have a serious adverse event reporting system in place and requires reports of serious adverse events that occur on or after January 1, 2006 to be reported to the ISDH. The rule requires the facility's quality assessment and improvement program to review incidents and determine whether a serious adverse event occurred. If a serious adverse event occurs, the facility must report the event to the ISDH not later than fifteen (15) working days after the facility's quality assessment and improvement program determines that a serious adverse event occurred. Data submission will occur utilizing the ISDH Web-based portal system. The ISDH is required to analyze and publish the data no less than annually.

Fiscal Impact

Indiana Code 4-22-2-28(c) requires an agency to submit to the Office of Management and Budget any proposed rule with an estimated economic impact of greater than five hundred thousand dollars ($500,000) on all persons regulated by the rule. After the preliminary adoption of such a rule, the Office of Management and Budget must prepare a fiscal impact statement concerning the effect that compliance with the proposed rule will have on the state and all persons regulated by the proposed rule.

The department reviewed the proposed rule to determine whether the total economic impact of the rule on regulated persons will exceed $500,000. The department determined, based on the information available at the time of the rule promulgation, that the proposed rule does not have an estimated economic impact of greater than five hundred thousand dollars ($500,000) on the persons regulated by the rule. The ISDH therefore did not submit the proposed rule to the Office of Management and Budget prior to the rule being adopted.

Economic Impact on Small Businesses

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

IC 4-22-2.1-4 defines a small business as any person, firm, corporation, limited liability company, partnership, or association that:

(1) is actively engaged in business in Indiana and maintains its principal place of business in Indiana;
(2) is independently owned and operated;
(3) employs one hundred (100) or fewer full-time employees; and
(4) has gross annual receipts of five million dollars ($5,000,000) or less.

The ISDH licenses 123 ambulatory surgery centers. The ISDH does not have data on the gross annual receipts of ambulatory surgery centers. Based on factors such as the number and type of procedures performed at the center, the ISDH estimates that fewer than twenty-five percent of centers would meet the definition of a small business. The ISDH therefore estimates there to be no more than thirty ambulatory surgery centers that are small businesses. The North American Industry Classification System classifies these institutions as ambulatory surgery centers (NAICS 621493).

In 2005, a public law was passed by the Indiana General Assembly requiring the licensing of abortion clinics beginning July 1, 2006. The ISDH has not yet begun the licensing of abortion clinics so does not have a definitive number of these clinics. The ISDH estimates the number of abortion clinics to be nine. The North American Industry Classification System classifies these institutions as abortion clinics (NAICS 621410).

In 2005, a public law was passed by the Indiana General Assembly requiring the licensing of birthing centers. Rules allowing to the licensing of birthing centers became effective on March 5, 2006. The ISDH has not yet begun the licensing of birthing centers so does not have a definitive number of these centers. The ISDH estimates the number of birthing centers to be five. The North American Industry Classification System classifies these institutions as midwives' offices or centers (NAICS 621399).

In summary, the number of small businesses impacted by this rule is likely less than forty-four.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

The economic impact of the serious adverse event reporting rule on ambulatory surgery centers, abortion clinics, and birthing centers is minimal. Ambulatory surgery centers are federally certified and state licensed. Abortion clinics and birthing centers are state licensed. Pursuant to existing certification and licensing standards, the health care facilities regulated by this rule are required to maintain records and ensure quality care. Existing rules and regulations require the regulated businesses to have a quality assurance committee and system. Each facility's quality assurance program is required to review and address quality of care issues. Existing rules and regulations would therefore require that the health care facility review serious adverse events and develop and implement a plan to address those events.

Initial start-up expenses:

This rule will require ambulatory surgery centers, abortion clinics, and birthing centers to gather and report serious adverse event data. To implement and achieve compliance with the rule, the facilities may have to modify current reporting policies and procedures in order to add the serious adverse event reporting. The facilities will need to ensure preparation, completion, and submission of required data. Because the reports will be submitted through the ISDH Web-based portal system, the facility will need to designate an individual to submit the reports and that individual will need to register on the system. The total estimated employee compensated time per facility for initial start-up compliance during the first year is twenty (20) hours. The ISDH expects these activities to be coordinated and performed by a compliance officer or director of nursing. The estimated total start-up expense based on estimated labor rates is $500 [20 hours x $25/hour].

Recurring expenses:

The rule will require the health care facility to determine whether a reportable serious adverse event occurred and, if so, report that event to the ISDH. The reporting of a serious adverse event is essentially a two-step process. The rule requires that the facility quality assessment and improvement program review reported medical errors to determine whether a reportable serious adverse event occurred. Under existing facility licensing rules, the facility quality assessment and improvement program is already required to review this kind of information so that component of the rule should not result in an added expense for the facility. If the program determines that a reportable serious adverse event occurred, the rule requires the facility to report serious adverse events within fifteen (15) working days of the determination by the quality assessment and improvement program. Reporting occurs through a Web-based portal system and only takes a couple of minutes to do per reportable event. The time required for gathering the information, determining whether reportable, and filing the report is likely no more than two (2) hours per serious adverse event. For facilities with few or no reportable errors, the cost is proportionately lower. Facilities reporting a significant number of errors would incur costs proportionately higher. Assuming one event per month, the estimated recurring annual expense is $600 [12 events x 2 hours x $25/hour].

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

Based on the above assumptions, the average first year expense is $1,100 [$500.00 start-up costs plus $600 recurring expenses] per facility. The total annual cost on small businesses for the initial year is therefore $48,400 [44 small businesses x $1,100 per facility].

The average expense for subsequent years is $600 per facility. The annual ongoing cost to the small businesses is therefore approximately $26,400 [44 small businesses x $600].

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

IC 16-21 requires the ISDH to license and regulate ambulatory surgery centers, abortion clinics, and birthing centers. The statute requires the ISDH to adopt rules to ensure quality assurance standards at the regulated facilities. Additionally, rules and regulations require the facilities to

maintain a quality assurance program. The ISDH believes the proposed rules are within the requirements established in applicable statutes, rules, and regulations.

Patient safety is of significant concerns to all Hoosiers. Medical errors have been identified in studies such as the Institute of Medicines 2000 report entitled *To Err is Human* as a significant problem in ensuring health care quality. The ability to collect data on serious adverse events is an important step towards analyzing information in order to improve health care quality through decreasing medical errors. The reduction of serious adverse events would decrease operating costs for health care facilities.

5. Regulatory Flexibility Analysis

A. Establishment of less stringent compliance or reporting requirements for small businesses.

In order to ensure the ability to obtain complete data, the reporting requirements are the same for all health care providers. The reporting requirement is very minimal. The facility is only required to report the classification of the serious adverse event and the quarter in which it occurred.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

Because the reporting requirements are minimal, there was no need to establish less stringent schedules or deadlines for small business compliance.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

It is expected that the health care facility's quality assessment and improvement program will meet periodically and review any serious adverse events gathered during the period since their last meeting. The program will therefore be able to consolidate events in an efficient manner. There are no other reporting requirements imposed by the proposed rule.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

There are accreditation and certification organizations that have established performance standards for these health care facilities. The standards imposed by this rule were developed by the National Quality Forum in collaboration with health care providers.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

The health care facilities already have quality assurance programs in place pursuant to other requirements. This proposed rule adds a minimal reporting requirement that is negligible.

Conclusion

The economic impact of the proposed rule on small businesses is minimal. If the health care facility has no serious adverse events, there would be no economic impact on small businesses.

Submitted by,

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